Automated uretero-intestinal anastomosis with absorbable staples

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Abstract

The automated uretero-intestinal anastomosis with absorbable staples project is centered on improving the procedure to secure ureter tissue to a neobladder. The neobladder is formed from intestinal tissue after a cystectomy surgery has been performed to remove the original diseased bladder. Currently, a surgeon uses a manual suturing technique to secure the neobladder to each of the two ureters, however this process is time consuming and its success is entirely dependent upon the expertise of the surgeon. Our client requested that our team design and build a stapler that could safely and effectively attach the two tissues together in a single action. The stapler must be safe and easier for the surgeon to use than the current method. It must also create a water-tight seal between the two tissues. Additionally, we will develop bio-degradable staples to be used in the stapler. These staples should be able to form a seal between the two tissues, degrade within one to two months, and cause minimal damage to the tissues during stapler firing. After several stapler design iterations, we selected and fabricated our stapler prototype. We will follow up with an absorbable staple design and testing of the two products together next semester.

Introduction

In cases where cancer has invaded a portion of a patient's bladder wall, a cystectomy procedure must be performed to remove the affected tissue[4]. Following the procedure, a new bladder (neobladder) may be formed from intestinal tissue, which is then surgically connected to each ureter to restore urinary system function[3]. Currently, our client uses a manual suturing technique to attach the neobladder to the ureters, but this method is time-consuming and, given the small dimensions of the ureters, can be difficult for the surgeon. Additionally, the success of this surgery is dependent on the skill of the surgeon, leading to heterogeneous results among recovering patients. These problems could be eliminated using a stapler that would quickly and effectively attach the tissues in a single motion. We propose the following stapler design, as well as a design for the staples that would be fired by the device.

Background

Bladder Cancer and the Cystecomy Procedure

Bladder cancer is a widespread illness in the United States, with over 70,000 new cases diagnosed and over 14,000 deaths in 2010 alone[5]. In cases where cancer has invaded the muscle layer of the bladder, a radical cystecomy must be performed to remove the entire bladder, nearby lymph nodes, and part of the urethra [6]. With the entire bladder removed, the surgeon must create another receptacle for urine collection. One method is to attach a urostomy bag to the ureters for urine collection. The urostomy bag lies outside the patient and is emptied several times a day [4].

A more preferable option is for the surgeon to create a neobladder by forming a pouch from intestinal tissue. This neobladder can exist inside the body and function in a manner similar to the original bladder when attached to the ureters. Our client, Dr. Tracy Downs, works in the urology department at UW Hospital, where he frequently performs cystecomy procedures with neobladder construction. He has found that the attachment of the ureters to the neobladder, which is performed with a manual suturing method, can be difficult and time consuming given the small diameter of the ureters.

Problem Statement

The current suturing method used to attach the ureters to the neobladder during the cystecomy surgery is time consuming and difficult. Our client has requested that we design a circular stapler that securely attaches the ureter tissue to the neobladder in a manner that is easy for the surgeon and safe for the patient. We also aim to design absorbable staples that can be used in our stapler design. These staples must be biocompatible and not cause significant tissue damage during stapler firing, and must also degrade in the body within one to two months of insertion. Before this staple/stapler combination can be used in living humans, it will be necessary to test it on human cadavers and animals to ensure that the staple seal holds throughout the healing process.

Problem Overview

Our goal is to design a circular stapler that is easy to use for the surgeon, safe for the patient, and effective in creating a water-tight seal between the neobladder and ureter tissue. It must be able to be activated in one swift motion, increasing the ease of use for the surgeon operating. In addition, we must design staples to be used with our design that do not damage or irritate the tissue and will be absorbed by the body within one to two months of implantation. As ureters vary from 7.0 to 10.0mm in diameter depending on the patient, our stapler must be able to accommodate for these size differences while still creating a water-tight seal. During this procedure, the stapler and staples must also cause minimal damage to the surrounding tissue of the ureter and bladder.

Problem Motivation

When bladder cancer has spread to the muscular tissue of the bladder, a cystectomy is performed to remove cancerous tissue. For future urine storage, the preferred solution is to replace the original bladder with a neobladder constructed from a portion of intestine, which is attached to the two ureters. With this method, the patient is able to normally store and expel urine. This makes the neobladder preferable to a urostomy bag that requires frequent draining and replacement. The neobladder is created and established after the diseased bladder is removed. The surgeon attaches the ureters to the neobladder with a suturing technique in which two running sutures are used to connect the end of the existing ureter to the side of the neobladder. Surgeon's knots are then tied on the outside of the lumen, finishing neobladder implantation. Due to the small size of the ureter tissue, this procedure can be time consuming and difficult to perform. Our stapler and staple designs should improve the ease and efficacy of ureter attachment to the neobladder.

Design Constraints

The most important function of the stapler is the creation of a water-tight seal between the ureters and neobladder tissue. It must do this without causing significant damage to the tissue. It must also be easy to manipulate while in the body during surgery. The firing

mechanism of the stapler should be simple and ergonomic for the surgeon operating it. As is typical for tools used in surgery, the stapler must be disposable or able to be sterilized if it will be reused. As current staplers used for anastomosis carry a cost of $500[6], the cost of our stapler should be comparable.

The staple design will have three main constraints. First, the staples must be compatible with our stapler design; that is, able to be fired from the stapler through the ureter and neobladder tissue to create a tight seal without damaging the tissue. Second, the staples must be biocompatible and must not cause complications such as stones or infections. Lastly, the staples should safely degrade within the body, completely absorbing after the tissue has healed within 1 to 2 months after surgery.

Current Method

When in surgery, our client Dr. Downs currently uses a suturing technique to attach the ureters to the neobladder. Using biodegradable 4-0 monocryl sutures, he uses two running sutures to attach the end of the ureter tissue to the side of the newly created neobladder. Surgeon's knots are then tied on the outside of the lumen of the tissue, and the attachment is tested by filling the ureter with a small amount of saline solution to test for leakage. If the seal is water tight, the attachment is considered a success and the neobladder is situated in the correct anatomical position.

Competition

Staplers

There are several circular surgical staplers already existing on the market, including the Ethicon circular stapler[6] used in bowel reconstruction surgery. However, none of these existing models is suitable for our client's use in neobladder construction due to their size and operating mechanism. Existing staplers are fit for surgeries involving intestine, stomach, and esophagus, which are of significantly larger diameter than a ureter. To effectively connect the ureters to the neobladder, a portion of the stapler must pass through the ureter to draw together the two tissues – the large sizes of the existing staplers would make such a task impossible.

Staples

This semester, the majority of our focus has been the creation of the stapler. In attempt to simultaneously begin development on the staples during this semester, we created two staple molds which we will eventually use to fabricate absorbable staples. Once created, we will be able to test the compatibility of these staples with our device. We will also test mechanical properties such as degradation, compressive strength and tensile strength of the staples. Currently, absorbable staples are available for a variety of applications. One such staple is INSORB, which is used in place of a suture in subcutaneous incisions[3]. INSORB staples are composed of poly-glycolic acid (PGA) and poly-lactic acid (PLA), a common copolymer for biomaterial applications (the exact polymer ratio is not advertised). They measure approximately 3 mm x 4 mm, similar in size to the staples for our application. They are designed to degrade over a period of months. In the spring semester, we will begin to develop similar staples for the stapler using a combination of PGA and PLA, though to first verify the efficacy of our stapler we could potentially use the INSORB staples. Additionally, the existence of such products on the market validates the decision of designing the stapler first – there currently exists no device like the one we propose in this report, yet absorbable staples are already available for certain applications.

Alternate Designs

Miniaturized Ethicon

Beginning early on and throughout the development process, the Ethicon endo-stapler was the main inspiration and model for the current design. The stapler serves as an example of a device which successfully links two pieces of tube-like tissue together, creating a tight seal. The first design idea entailed shrinking this Ethicon stapler down so that it would fit within the small confines of a ureter. However, this idea had a glaring flaw. While the goal of this device is indeed to link ureter tissue and

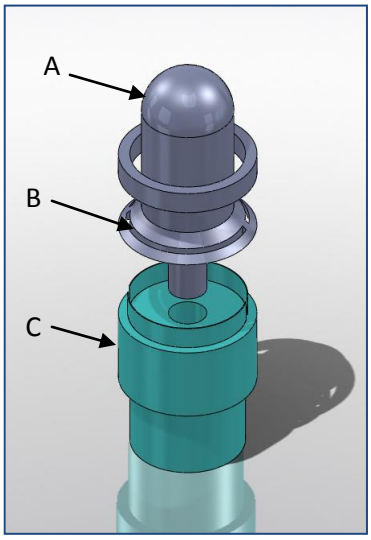

Figure 1 - New anvil design

bladder tissue together to form a tight seal, the logistics of the procedure are not conducive to using the Ethicon stapler. The Ethicon stapler functions by first closing the ends of the two ends of the tubular organ, either by stitching closed or suturing the anvil in place. The two closed ends are connected, and a staple ring is fired as a ring of tissue is simultaneously cut out and extracted. To mimic this procedure in connecting ureters to a bladder, a very small anvil would have to be sutured into the ureter. Not only would this be a tedious task, but if the surgeon is required to use a suture on an exceedingly small strip of tissue such as the ureter, he or she may as well just suture the ureter to the bladder. In essence, the stapler would be obsolete and would serve no improvement over the current suturing method. As a result, while the Ethicon endo-stapler remains an important guiding direction in the design process, the design idea of employing a simple size reduction while keeping the same elements will not suffice for the purpose of this project.

New anvil design

Our new anvil design features a tapered anvil (Fig1-A) that will be inserted into the ureter. The ureter tissue is secured in place on the anvil with a ring clamp (Fig1-B) that has two halves so that it may be secured and removed from the circular ureter. The ring clamp also serves as a base against which the firing mechanism (Fig1-C) will push the staples to bend them back around. There are two different ways that the neobladder tissue can be secured against the ring clamp using this new anvil design.

Securing bladder tissue above ureter

When the bladder tissue (Fig2-D) is secured above the ureter (Fig2-B), the clamping pressure applied to the bladder tissue is provided by the ring clamp. In this method, the anvil (Fig2-A) will be placed in the ureter and used to pull the ureter tissue below the bladder tissue. This procedure will require a hole to be made in the neobladder tissue before the ureter tissue is pulled through so that the whole base of the anvil will fit. This is less than ideal because the bladder tissue may undergo unnecessary damage in the process. The ring clamp (Fig2-C) will then be applied to

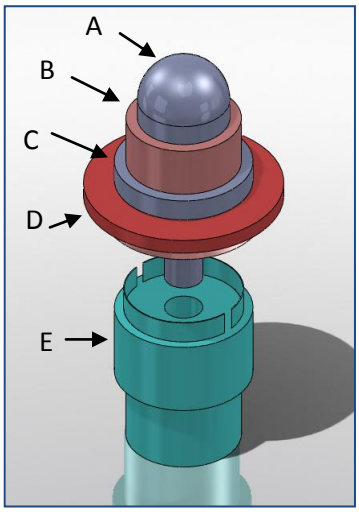

Figure 2 Bladder secured above ureter tissue

secure the ureter and bladder tissue in place at the appropriate tissue compression. The firing mechanism (Fig2-E) will be brought up and secured to the anvil. The mechanism will then fire the staples into the ring clamp where they will be bent over, securing the tissue. After the staples are fired, the anvil will be pulled out with the firing mechanism through the bladder. The two halves of the ring clamp will be separated and removed above the anastomosis.

Securing bladder tissue below ureter

When the bladder tissue (Fig3-D) is secured below the ureter (Fig3-B), the clamping pressure applied to the bladder tissue is provided by the anvil (Fig3-A) pushing against the firing mechanism (Fig3-E). This is less than ideal as it is better for both tissue types to be clamped with exactly the same pressure. In this method, the anvil will again be placed in the ureter. The ring clamp (Fig3-C) can then be placed on the anvil to secure the ureter tissue at the appropriate compression. For this procedure, it will be necessary to form a very small hole in the neobladder tissue so that the bottom process of the anvil can be passed through and secured in the firing mechanism. The firing mechanism will be brought up through the neobladder and secured to the bottom process of the anvil. The mechanism will then fire the staples into the ring clamp where they will be bent over, securing the tissue. After the staples are fired, the anvil will be pulled out with the firing mechanism through the bladder. The two halves of the ring clamp will be separated and removed above the anastomosis.

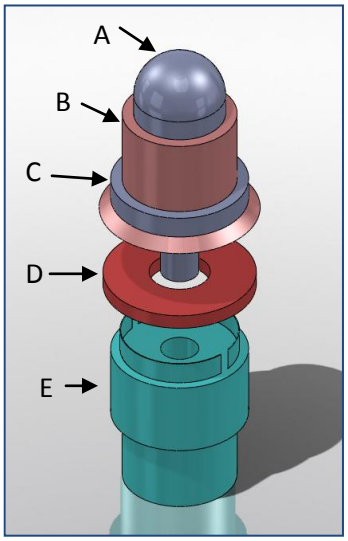

Figure 3 Bladder secured below ureter tissue

Design Matrix

Upon elimination of the miniaturized Ethicon stapler as a design option, attention turned towards the two remaining design alternatives. Though the designs are essentially constructed the same, they vary in their application. These designs were rated on five different criteria: ease of use, security/clampability, limited tissue damage, ease of construction, and aesthetics (Table 1). Ease of use had the most weight of any category because this design mainly revolves around facilitating an existing procedure. Security of the tissue is of obvious importance because the

two tissues must be tightly clamped to ensure a neat staple line devoid of leaks. However, the ureter and bladder tissue should not be clamped too tightly as to mitigate tissue damage, hence the limited tissue damage category of the matrix. In addition, ease of construction is an important factor in determining the feasibility of the design option. The final product should be designed well enough to serve its intended purpose, though an overly ambitious design would surely hinder the ability to produce something in a timely fashion. Of lesser importance is the final category of aesthetics. For our prototype, an emphasis of function over style was preferred.

Design	Security/ Clampability **(20)**	Ease of Construction **(20)**	Aesthetics **(10)**	Ease of Use **(30)**	Limited tissue damage **(20)**	Total
Ring clamp – ureter above bladder	15	18	7	22	18	80
Ring clamp – ureter below bladder	18	18	7	25	16	**84**

Table 1 Design matrix

In applying this matrix to our remaining design choices, it was evident that securing bladder tissue above ureter was the best option. This design choice incorporates a technique on the part of the surgeon which imparts greater tissue security. It can also be done in one clamping motion, where the ureter tissue and bladder tissue are both clamped between the ring clamp and bottom part of the stapler. If the ureter tissue is placed on top of the bladder, it must first be situated and clamped in place by the ring clamp, then clamped again by the bottom of the stapler on the underside of the bladder. This dual clamping could lead to movement during steps and therefore sloppy staple lines. Because the ureter tissue is below or inside the bladder, there will be less leakage. In contrast, if the ureter is splayed and stapled on top of the bladder tissue, there may be leakage if the pressure on the staple line is too great. When the staple line is below the bladder tissue already, it will not have to come into contact with this staple line as fluid will simply drain below into the bladder. However, this method comes with one disadvantage – it

requires a larger incision to be cut into the bladder tissue to feed the bottom of the anvil through, which is necessary for attaching with the bottom part of the stapler and achieving the correct tissue compression for firing the stapler. Overall, we believe that attaching ureter tissue underneath the bladder will be the best method for automated uretero-intestinal anastomosis.

Final Design

The final design we selected to pursue was the new anvil design securing the bladder tissue above the ureter. After additional consideration of the ureter tissue mechanics, we adjusted the design of the anvil and ring clamp so that the firing mechanism we developed will have the space necessary to fire the staples.

Anvil

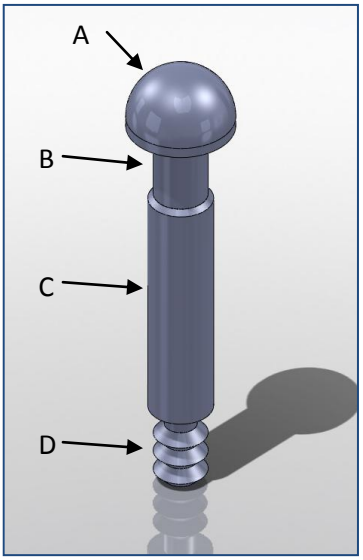

Figure 4 Anvil

The anvil portion of the final design is 10mm wide at the base of the semi-circular head (Fig4-A). The anvil is pushed into the ureter where it should fit snugly as the ureter has a normal internal diameter of 7-10mm. The neck of the anvil will then be pulled down through a small hole in the neobladder until the lip of the ureter is below the neobladder tissue. Just below the head of the anvil, the neck is 5mm in diameter and 7.5mm long (Fig4-B). The ureter tissue is secured to the anvil using a two-sided ring clamp (described below) that clamps the tissue to this 5mm diameter portion of the anvil neck. Just below the ring-clamp region, the neck of the anvil expands to 6mm in diameter to prevent the ring clamp from slipping down (Fig4-C). This should also promote the ureter tissue to splay out slightly just below the ring clamp. The 6mm in diameter spacer portion of the anvil neck is 25mm long. Below the spacer portion of the anvil, a series of three discs serve as a means to secure the anvil in the firing mechanism (Fig4-D).

Ring clamp

The ring clamp has an internal diameter of 6mm and an external diameter of 20mm. The ring clamp has two sides (Fig5) so that it may be attached and removed from the ureter, which is circular. The two sides of the ring clamp fit together like pieces of a puzzle. The pieces are identical with one side that has an extrusion and one side that has a slot (Fig5-C). It has circular divots (Fig5-A) surrounding the base of its internal diameter that serve as a base against which the firing mechanism can fire the staples. Each of the divots is 0.5mm wide and 1.0 mm long. Two divots form a whole unit into which a staple can be fired. There are six staple units in a first inner ring (Fig6-A), and a staggered row of six staple units (Fig6-B) in a second outer ring. The inner ring is 0.25mm from the inner edge and the outer ring is 0.5mm outside the inner ring. These staggered double rows will ensure that the staples form a water tight seal on the tissue. The divots are spaced evenly around the ring, with each divot pair 60 degrees apart. Each of these extrusion pairs allows for a 2.5mm wide staple to be fired and bent around.

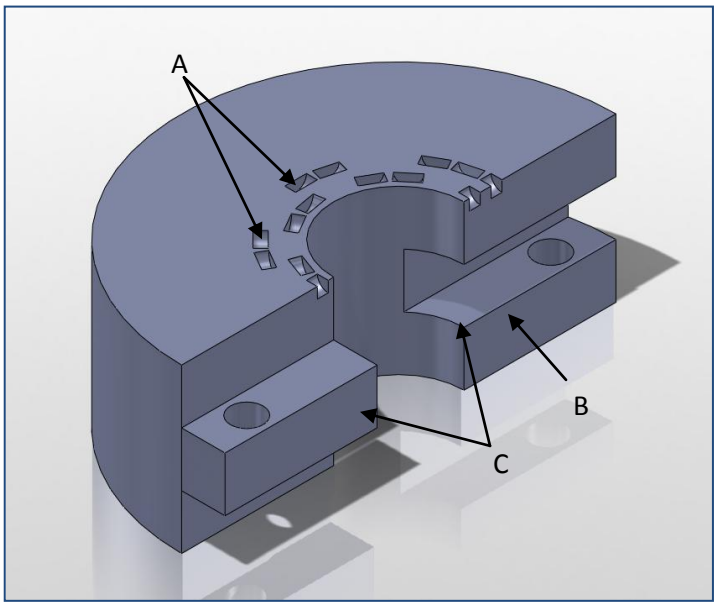

Figure 5 half of the ring clamp

As an added measure of security and stability, we added holes in the edges of the ring clamp (Fig5-B) where they fit together so that a pin may be placed through both pieces of the ring clamp, ensuring that remain locked together for the entire procedure. After receiving the

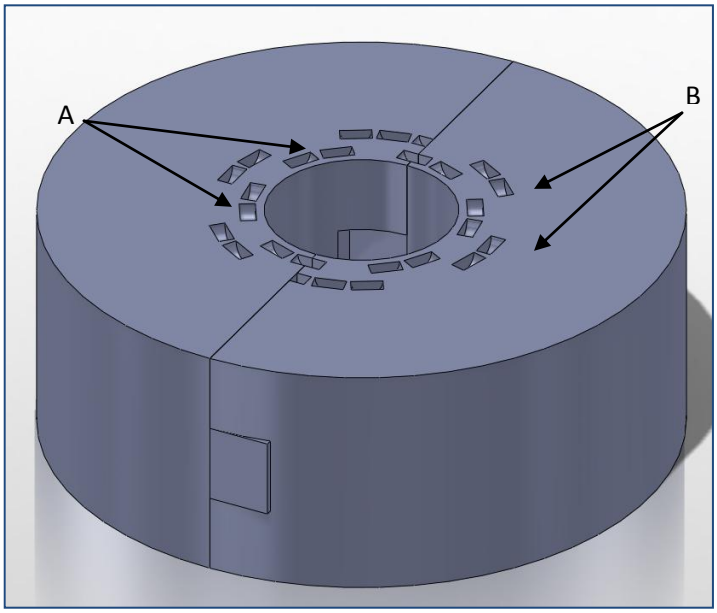

Figure 6 Both sides of the ring clamp put together

fabricated parts, we realized that these holes may be redundant because the pieces already fit together quite snugly.

Firing mechanism (picture)

In order to propel surgical staples through the bladder and ureter tissue, we implemented a trigger or ejection mechanism. As a preliminary design, we chose to apply the same trigger mechanism utilized in the Ethicon. As seen below (Figure 7), this mechanism involves a pin, handle, and actuator in order to perform translational movement. A key component involved in this mechanism is the plastic sheath or casing which surrounds and encapsulates the trigger components and allows for free rotation of the trigger around the placement pin.

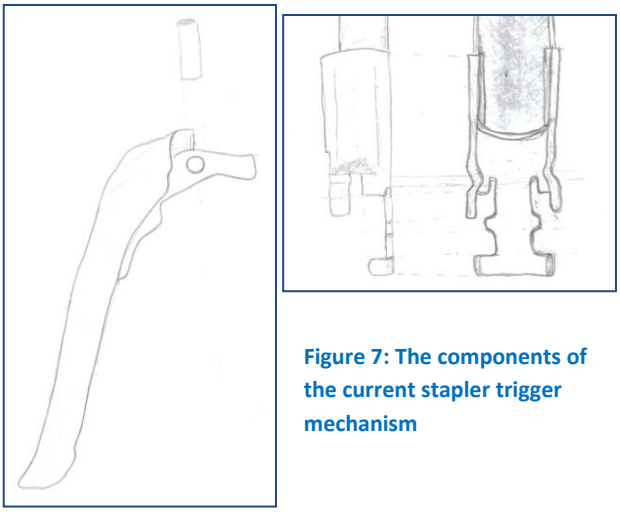

Figure 7: The components of the current stapler trigger mechanism

Although we have not formulated a trigger, we aimed to improve on the current trigger system by postulating the design seen below. The trigger in this instance will be a warped member, fitted to rotate around a pin which is held in place by a back plate which will be welded onto the trigger arm. Encircling this pin are two torsion springs which allow for two factors to be placed in the design. First, the force applied to the staples can be limited by adequate spring constants. Second, there is recoil of all ejection components after force is removed from the trigger. According to one study performed at the University of Michigan[1], it was determined that the minimum force required to staple a few sheets of paper together was approximately 50N or 11.24 lbs. However, this force is higher than it needs to be, considering how small, fragile staples and the thin ureter and bladder tissue combination. For simplicity it is assumed that a vertical force of no more than 5lbs will sufficiently eject from the casing, puncture all according tissues and contact the ring clamp with enough force to bend the staple ends.

Taking a 5lb force into account and using the torsion spring equation:

$$k=PM/\alpha$$

With the spring moment arm M=1.5 in and the amount of rotation angle $\alpha = 90^{\circ}$; a spring constant of .0833 will be sufficient to transgress the trigger. The pivot pin will be kept in place with a plastic sheat or casing that encircles the remaining parts of the trigger and forms the bottom half of the stapler. The end of the trigger handle is concave in shape and has a hole in it. The concave shape serves the purpose of allowing the trigger to push up the firing rod smoothly and sufficiently after it makes contact. The hole in the middle allows for the rod holding the staple cartridge to run through and connect to the base of the plastic casing.

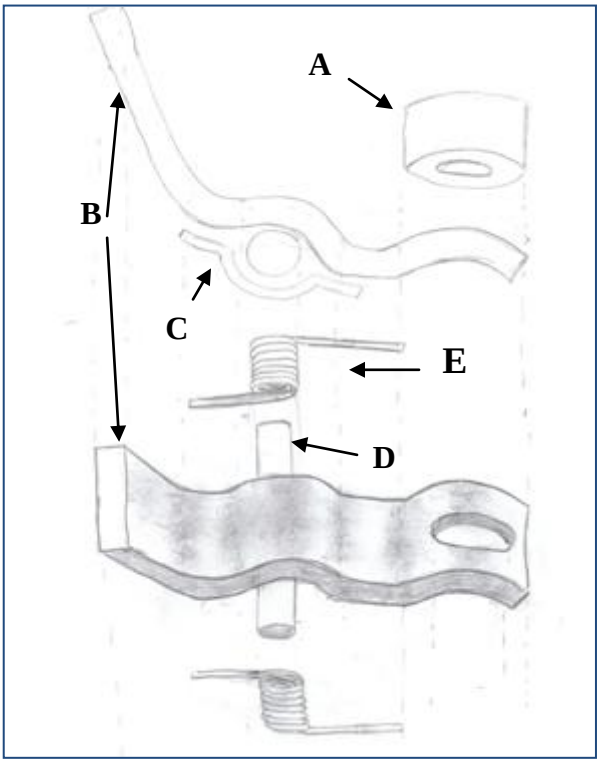

Figure 8: This figure represents all the members of the trigger system. A. Hollow rod which holds staple forming teeth B. Warped trigger handle C. Securing back plate D. Pivot pin E. Torsion spring.

Staple cartridge

The staple cartridge serves as a vehicle to deliver the staples to the tissue. The cartridge has the capacity to hold 12 staples total, 6 in an inner ring and six in an outer ring. It has an internal diameter of 6mm, and an external diameter of 10.5mm. The staples are fit snugly into holes spaced evenly around the circular cartridge in two staggered rows that match up exactly with the divots in the ring clamp. The holes in the staple cartridge have dimensions of 2.7mm x 0.6mm. This

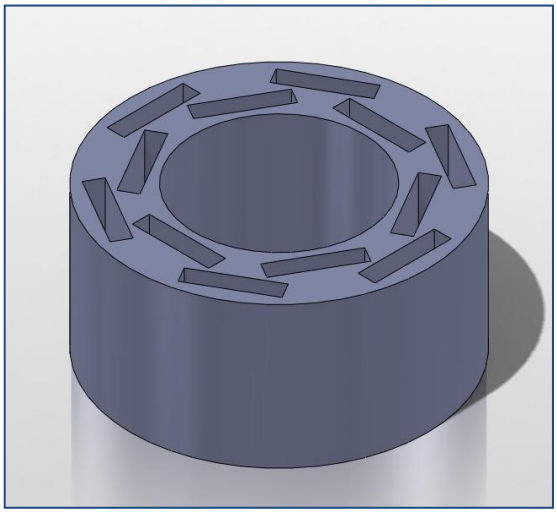

Figure 9 Staple cartridge

is slightly larger than the size of the staples and the size of the staple forming teeth to allow for smooth firing with minimal friction.

Staple forming teeth

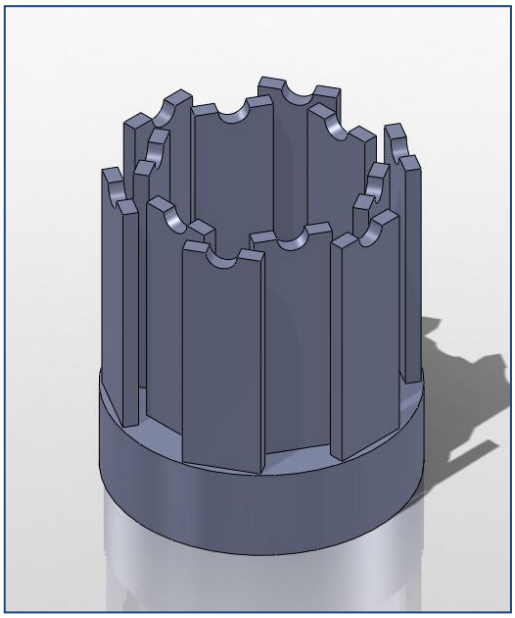

Figure 10 Staple-forming teeth

The staple forming teeth are used in conjunction with the firing mechanism to fire the staples into the ureter and bladder tissue. There are 12 staple-forming teeth that are spaced to match up exactly with the holes in the staple cartridge and the divots in the ring clamp. The teeth are 8mm tall and have a semicircular dip in the top (1.0mm in diameter) to promote appropriate staple bending. The staple teeth have cross sectional dimensions of 2.5mm x 0.5mm and sit on a ring with an inner diameter of 6.0mm and an outer diameter of 10mm. When the firing mechanism is utilized, the staple forming teeth push through the staple cartridge, delivering the staples through the ureter and neobladder tissue and into the ring clamp, where the staples bend over back into the ureter and neobladder tissue.

Testing

Physician Assessment

Because our project was proposed to help make our client's work easier and more efficient, our first test will qualitatively measure our products function using the opinions of our client and his colleagues. To do this, we will demonstrate to how the stapler would work in connecting the ureter and bladder tissues, and assess how well they believe the stapler will work in practice using a five point scale. Through this test we gained approval of our design and firing mechanism by the consumers of our project, which we consider essential for our final model to be clinically successful.

Future Work

Currently, our design consists of four components: an anvil, ring clamp, staple cartridge and firing mechanism. While these parts theoretically work well together, we need to combine them in a sleek apparatus and establish one swift firing motion to fire the staples into the tissue. We are in the process of designing a mechanism that can push the staples up through the staple cartridge and into the tissue. Metal staples will be used to test the efficacy of our stapler in firing staples and creating a water tight seal. The security of the water tight seal will be tested with a burst test, to ensure that the maximum amount of force exerted by fluid in the ureter on the anastamosis does not break the seal. A burst test applies hydraulic pressure at a controlled rate and can use high speed data acquisition to capture pressure and flow data at the time of the burst.

After confirming that our design does fire metal staples correctly (creates a water tight seal), we plan on fabricating a composite PGA/PLA staple that will have a degradation profile of approximately 30 days when in contact with bladder tissue, ureter tissue and bodily fluids passing through this system. The staples should be able to promote tissue healing and regeneration so as to secure the connections between the ureters and the neobladder for the duration of the patient's lifetime. PGA and PLA are polyesters that undergo bulk degradation via hydrolysis. PGA contains an ester linkage, and degrades very quickly via hydrolysis, while PLA has a slower degradation rate. PGA is commonly used in absorbable suture material and PLA is stronger and can be used in fabrication of bone screws and plates. Polylactic-co-glycolic acid (PLGA) can be made by combining PGA and PLA in varying ratios. This combination creates a strong, yet degradable polymer, ideal for use as an absorbable staple material. Proteins can adsorb onto the surface of PLGA which should encourage cell adhesion and tissue regrowth and regeneration surrounding the anastomosis.

The degradation profiles of the following three different ratios of PGA/PLA will be tested: 40:60, 50:50 and 60:40. Ideally one of these ratios will present a degradation profile of approximately 30 days, and allow for tissue healing and regrowth. If this is the case, we will do further testing on that composition to pursue in our staple design. The three different ratios would not only be tested for their degradative properties, but also for their rigidity and flexibility. The final material must be rigid enough to be molded into a staple and fired into tissue, but must also be able to bend through the tissue to create a water-tight seal.

We have already fabricated a mold for forming these staples which we will use by pouring in these different polymer compositions and allowing them to set. There are several different staple designs in the mold which we will also test to determine what shape of staple is most appropriate to achieve the correct security and degradation profile.

With the stapler and the staples, we will then complete animal cadaver testing and eventually human cadaver testing of our device. Before utilizing our device in living patients, we must determine if the stapler can fire the staples through ureter and bladder tissue of a cadaver to create a water-tight seal. It is important to complete these tests on human tissue so that the thickness and elasticity characteristics of the tissue being stapled are accurate.

After finalizing the stapler, firing mechanism, and the staples, we plan to fabricate a mold for the individual pieces of the stapler. Because the parts are so small and intricate, it would be most efficient to create a mold for generating the parts. Using this method, the mold could be filled with an appropriate biocompatible material and the parts for the stapler could be fabricated in mass quantities at a low price.

Ethical Considerations

The main ethical consideration of our project is patient safety. As our final product will be used in surgery and will be in direct contact with patient tissue, it must be considered safe in several respects. It must be biocompatible and not provoke infection. While it must puncture the bladder and ureter tissue to create an effective seal, it should not excessively damage the tissue during compression. The constructed perforations in the two tissues should be minimized to avoid tearing or extensive damage to the tissue, which would likely result in improper healing.

In addition to stapler safety concerns, there are staple safety concerns because the staples will be embedded into patient tissue for an extended period of time. Staple biocompatibility is of extreme importance to avoid infection or kidney stone formation within the ureter and bladder tissue.

Another ethical consideration concerns the usability of our prototype. While stapling the two tissues together would certainly be more time-effective than suturing, our design contains many small, moving parts and surgeons will likely need to have some sort of training on how to

use our device before being able to employ it in surgery. However, even with the added time and effort of training, we believe our stapling mechanism will still be simpler and easier to use than the current suturing method, while maintaining the same level of effectiveness.

Budget

Our client has given us a budget of $3000-$5000 for fabrication of the stapler and staples. We plan on spending the majority of this budget to create molds of our final parts when we have completely finalized our designs. In order to create prototypes and ensure that our part designs do work together properly, we used *C-Ideas Rapid Printing Solutions*, a 3D printing company, to fabricate our parts. We have spent $115.30 so far on the rapid prototyping of our device.

Conclusion

When a radical cystectomy is performed, formation of a neobladder from intestinal tissue is the preferred form of future urine storage. Currently, the manual suturing method used by surgeons to attach the patient ureter tissue to the neobladder is both time consuming and difficult for the surgeon, and the suture lines and stitch count vary from patient to patient. To improve the efficacy of ureter attachment and ensure consistent results regarding the seal, our team is in the process of producing a circular surgical stapler and absorbable staples that could be used in surgery. By using our stapler, creating a water-tight seal between the ureter and neobladder tissue can be accomplished in a single motion that is easy to use for the surgeon. Our stapler will also allow for uniform seal formation for all patients, which leads to a homogeneous recovery that is easier to assess and monitor. This semester, our team accomplished designing and prototyping our stapler and firing mechanism, as well as physician assessment testing of the stapler and developing possible staple designs. Next semester, we plan on further testing of the stapler prototype, including evaluating the efficacy of our stapler in creating water-tight seals using animal and human cadaver tissue, as well as conducting a burst test to evaluate the strength of the created seal. We will also continue development of absorbable staples for the stapler, including the testing of PGA/PLA mixes to determine the ratio that provides the desired degradation time of approximately 30 days. Depending on the future results of these tests, alterations may be made to our current design to ensure that our device successfully meets our client's expectations and fulfills its intended role in surgery.

Appendix A: References

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2. Ethicon Endo-Surgery. 2010. Ethicon Endo-Surgery, Inc. 1 November 2010. <www.ethiconendosurgery.com/>

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4. Lerner, S.P., Schoenberg, M.P. *Textbook of Bladder Cancer*. Florida: Taylor and Francis, 2006.

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Appendix B: Product Design Specifications

Client requirements:

- Head needs to be less than 10 mm in diameter
- Needs to be able to pass through the neo-bladder to perform anastomosis
- Must be simple to operate with a single squeezing motion required to fire staples
- Must be faster for experienced surgeons to operate than tying sutures
- Must succeed in delivering a staple line that is consistent across multiple procedures
- Must be sterile
- Can be reusable or one-time use if comparable in price to other similar products on the market for other procedures (ie the Ethicon endo-stapler for colorectal anastomosis)
- Must create a water-tight seal of the ureter to the neo-bladder
- Must be usable for open surgery

Design requirements:

1. **Physical and Operational Characteristics**

   a. *Performance requirements*: Will be used for a single patient to perform automated anastomosis which secures two ureters to a neobladder. If product can be autoclaved, it could be used for multiple patients. If being used for multiple surgeries, stapler must have a mechanism to re-load staples between uses.

   b. *Safety*: Must not damage surrounding tissue in the abdominal cavity, bladder or ureters. Must create a secure, water-tight seal with both ureters to allow for normal function of the kidneys post-surgery.

   c. *Accuracy and Reliability*: Must accurately deliver staples to secure the ureters to the neo-bladder. The seal created must be water-tight. Repeatable results across procedures is important.

   d. *Life in Service*: The device is intended to be single use, but if its materials can be autoclaved could potentially be used for multiple patients.

   e. *Shelf Life*: There are no degradable components to our design. Theoretically the device should have an indefinite shelf life prior to use when properly stored.

f. *Operating Environment*: The device will be operated in a hospital. It needs to be sterile to avoid cross-contamination. It will be disposed of after being used unless it can be autoclaved and sterilized.

g. *Ergonomics*: Should be easy to operate by one experienced surgeon.

h. *Size*: The head of the device (and thus diameter) must be smaller than 10 mm to fit within the spatulated ureter. Additionally, the head of the device may vary in size depending on the size of the ureter in the patient. The entire device must be long enough to fit through the neo-bladder and ureter in an open surgery.

i. *Weight*: The device should be easy to operate inside a body during open surgery, and thus shouldn't exceed 2-5 lbs.

j. *Materials*: The material used should not pit or rust easily. It should be sturdy and maintain its shape. It should not be magnetic to avoid any unintended reactions in the operating room.

k. *Aesthetics, Appearance, and Finish*: Device should be aesthetically pleasing, sleek and free of rough edges that could damage tissue unintentionally during the procedure.

2. Production Characteristics

a. *Quantity*: 1 deliverable.
b. *Target Product Cost*: Up to $500.

3. Miscellaneous

a. *Standards and Specifications*: Must be approved for safety and function by the surgeons utilizing the device. Must have IRB approval once used in humans with absorbable staples.

b. *Customer/Patient related concerns*: Must create a water tight seal after anastomosis is performed. Must not do damage to any other tissues in the body. As a second step in this project, the staples should degrade within 30 days to mitigate the risk of infection and pain in the patient.

d. *Competition*: There is currently no product made specifically for sealing the ureter to the neo-bladder during anastomosis. There is a similar product on the market for securing the colon back together after a section has been removed due to disease, however this device is far too large to be used for reconnecting ureters to a neo-bladder.